



[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Scientific Advisory Committee on Alternative Toxicological Methods;

Announcement of Meeting; Request for Comments

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: This notice announces the next meeting of the Scientific Advisory Committee on Alternative Toxicological Methods (SACATM). SACATM, a federally chartered external advisory group of scientists from the public and private sectors, including representatives of regulated industry and national animal protection organizations, advises the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM), the National Toxicology Program (NTP) Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM), and the Director of the National Institute of Environmental Sciences (NIEHS) and NTP regarding statutorily mandated duties of ICCVAM and activities of NICEATM. The meeting is open to the public and registration is requested for both attendance and oral comments and required to access the webcast. Information about the meeting and registration are available at <https://ntp.niehs.nih.gov/go/32822>.

DATES:

Meeting: September 19-20, 2019; begins at 9:00 a.m. (EDT) each day and continues until adjournment.

Written Public Comment Submissions: Deadline is September 12, 2019.

Register to Present Oral Comments: Deadline is September 12, 2019.

Registration for Meeting: Deadline is September 12, 2019 to attend in person and September 20, 2019 to view the webcast.

Registration to view the meeting via the webcast is required.

ADDRESSES:

Meeting Location: Crowne Plaza Crystal City – Washington, DC, 1480 Crystal Drive, Arlington, Virginia 22202.

Meeting Web page: The preliminary agenda, registration, and other meeting materials are at <https://ntp.niehs.nih.gov/go/32822>.

Webcast: The meeting will be webcast; the URL will be provided to those who register for viewing.

FOR FURTHER INFORMATION CONTACT: Dr. Elizabeth Maull, Designated Federal Official for SACATM, Office of Liaison, Policy and Review, Division of NTP, NIEHS, P.O. Box 12233, K2-17, Research Triangle Park, NC 27709. Phone: 984-287-3157, Fax: 301-480-3008, Email: maull@niehs.nih.gov. Hand Deliver/Courier address: 530 Davis Drive, Room K2021, Morrisville, NC 27560.

SUPPLEMENTARY INFORMATION:

Meeting and Registration: The meeting is open to the public with time scheduled for oral public comments; attendance at the meeting is limited only by the space available.

SACATM will provide input to ICCVAM, NICEATM, and NIEHS on programmatic activities and issues. Preliminary agenda items for the upcoming meeting include: (1) new approaches to the principles and practice of validation, (2) developing a next generation data infrastructure to support the development and implementation of

new approach methodologies (NAMs) for complex endpoints, and (3) translational impact and human relevance of NAMs. Please see the preliminary agenda for information about the specific presentations.

The preliminary agenda, roster of SACATM members, background materials, public comments, and any additional information will be posted when available on the SACATM meeting website (<https://ntp.niehs.nih.gov/go/32822>) or may be requested in hardcopy from the Designated Federal Official for SACATM. Following the meeting, summary minutes will be prepared and made available on the SACATM meeting website.

Interested persons may attend the meeting in person or view the webcast. Registration is required to view the webcast; the URL for the webcast will be provided in the email confirming registration. Individuals who plan to provide oral comments (see below) are encouraged to register online at the SACATM meeting website (<https://ntp.niehs.nih.gov/go/32822>) by September 12, 2019, to facilitate planning for the meeting. Individuals are encouraged to visit the website often to stay abreast of the most current information regarding the meeting. Individuals with disabilities who need accommodation to participate in this event should contact Ms. Robbin Guy at phone: (984) 287-3136 or email: guyr2@niehs.nih.gov. TTY users should contact the Federal TTY Relay Service at 800-877-8339. Requests should be made at least five business days in advance of the event.

Written Public Comments: Written and oral public comments are invited for the agenda topics. Guidelines for public comments are available at https://ntp.niehs.nih.gov/ntp/about_ntp/guidelines_public_comments_508.pdf. The

deadline for submission of written comments is September 12, 2019. Written public comments should be submitted through the meeting website. Persons submitting written comments should include name, affiliation, mailing address, phone, email, and sponsoring organization (if any). Written comments received in response to this notice will be posted on the NTP website, and the submitter will be identified by name, affiliation, and sponsoring organization (if any).

Oral Public Comment Registration: The preliminary agenda allows for several public comment periods, each allowing up to four commenters a maximum of five minutes per speaker. Oral comments may be presented in person at Crowne Plaza Crystal City – Washington, DC, 1480 Crystal Drive, Arlington, Virginia 22202 or by teleconference line. Registration for oral comments is on or before September 12, 2019, at <https://ntp.niehs.nih.gov/go/32822>. Registration is on a first-come, first-served basis, and each registrant will be assigned a number in their confirmation email. Each organization is allowed one time slot per comment period. After the maximum number of speakers per comment period is exceeded, individuals registering to submit an oral comment for the topic will be placed on a wait list and notified should an opening become available. Commenters will be notified after September 12, 2019, about the actual time allotted per speaker, and the teleconference number will be sent to those registered to give oral comments by teleconference line. If possible, oral public commenters should send a copy of their slides and/or statement or talking points to Robbin Guy by email: guyr2@niehs.nih.gov by September 12, 2019.

Meeting Materials: The preliminary meeting agenda will be posted when available on the meeting Web page <https://ntp.niehs.nih.gov/go/32822> and will be updated one week

before the meeting. Individuals are encouraged to visit this Web page often to stay abreast of the most current information regarding the meeting.

Background Information on ICCVAM, NICEATM, and SACATM: ICCVAM is an interagency committee composed of representatives from 16 federal regulatory and research agencies that require, use, generate, or disseminate toxicological and safety testing information. ICCVAM conducts technical evaluations of new, revised, and alternative safety testing methods and integrated testing strategies with regulatory applicability and promotes the scientific validation and regulatory acceptance of testing methods that more accurately assess the safety and hazards of chemicals and products and replace, reduce, or refine (enhance animal well-being and lessen or avoid pain and distress) animal use.

The ICCVAM Authorization Act of 2000 (42 U.S.C. 285l–3) establishes ICCVAM as a permanent interagency committee of NIEHS and provides the authority for ICCVAM involvement in activities relevant to the development of alternative test methods. Additional information about ICCVAM can be found at <http://ntp.niehs.nih.gov/go/iccvam>.

NICEATM administers ICCVAM, provides scientific and operational support for ICCVAM-related activities, and conducts and publishes analyses and evaluations of data from new, revised, and alternative testing approaches. NICEATM and ICCVAM work collaboratively to evaluate new and improved testing approaches applicable to the needs of U.S. federal agencies. NICEATM and ICCVAM welcome the public nomination of new, revised, and alternative test methods and strategies for validation studies and technical evaluations. Additional information about NICEATM can be found at

<http://ntp.niehs.nih.gov/go/niceatm>.

SACATM, established by the ICCVAM Authorization Act [Section 2851–3(d)], provides advice on priorities and activities related to the development, validation, scientific review, regulatory acceptance, implementation, and national and international harmonization of new, revised, and alternative toxicological test methods to ICCVAM, NICEATM, and Director of NIEHS and NTP. Additional information about SACATM, including the charter, roster, and records of past meetings, can be found at <http://ntp.niehs.nih.gov/go/167>.

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